WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6:

A61K 9/20

(11) International Publication Number:

WO 97/48385

A3

(43) International Publication Date:

24 December 1997 (24.12.97)

(21) International Application Number:

PCT/US97/10737

(22) International Filing Date:

20 June 1997 (20.06.97)

(30) Priority Data:

08/667,238

21 June 1996 (21.06.96)

US

(71) Applicant: TEMPLE UNIVERSITY OF THE COMMON-WEALTH SYSTEM OF HIGHER EDUCATION [US/US]; Broad & Oxford Streets, Philadelphia, PA 19122 (US).

(72) Inventor: KIM, Cherng-Ju; 107 Drayton Circle, Lansdale, PA 19446 (US).

(74) Agent: SCHIFFMILLER, Martin, W.; Kirschstein, Ottinger, Israel & Schiffmiller, P.C., 551 Fifth Avenue, New York, NY 10176 (US).

THICKNESS 04.0: 106

(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TT, UA, UZ, VN, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

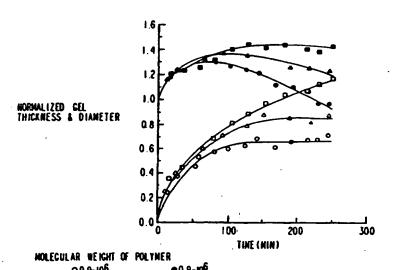
Published

With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(88) Date of publication of the international search report:
19 February 1998 (19.02.98)

(54) Title: CONTROLLED RELEASE TABLET



(57) Abstract

A controlled release tablet including a pharmaceutical agent and an excipient. The excipient includes at least about 60 % of a water swellable polymer and a lubricant. The water swellable polymer is chosen such that the swelling rate of the polymer is equal to the dissolution rate of the swollen polymer. The excipient may also include such other ingredients as diluents, fillers, binders, solubilizers, emulsifiers, and other pharmacologically inactive compounds. The polymer is chosen with the pharmaceutical agent in mind such that the tablet will be fully dissolved at the same time that the last of the pharmaceutical agent is released.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	Fí	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	. MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav	TM	Turkmenistan
BF	Burkina Faso	GR	Greece		Republic of Macedonia	TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago .
BJ	Benin	1 E	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	1L	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Cango	KE	Kenya	NL	Netherlands	YU	Yugoslavia
СН	Switzerland	KG	Kyrgyzstan	NO	Norway	zw	Zimbabwe
CI.	Côte d'Ivoire	KP	Democratic People's	NZ	New Zealand		
CM	Cameroon		Republic of Korea	PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

INTERNATIONAL SEARCH REPORT

onal Application No

		PCT/US 9	7/10737	
A. CLASS IPC 6	HEICATION OF SUBJECT MATTER A61K9/20			
According	to International Patent Classification(IPC) or to both national classific	ation and IPC		
	S SEARCHED locumentation searched (classification system followed by classification		_	
IPC 6	A61K			
Documenta	ation searched other than minimumdocumentation to the extent that s	uch documents are included in the fields s	earched	
Electronic	data base consulted during the international search (name of data ba	ise and, where practical, search terms use	d)	
C. DOCUM	IENTS CONSIDERED TO BE RELEVANT			
Category '	Citation of document, with indication, where appropriate, of the rek	avant passages.	Relevant to claim No.	
X	C. J. KIM: "Drug release from co polyox-wsr tablets" JOURNAL OF PHARMACEUTICAL SCIENCE vol. 84, no. 3, 1995, pages 303-306, XP002018917	·	1,3,4, 7-9,13, 17, 19-23, 27-33, 37,38	
	see the whole document		37,38	
X	EP 0 661 045 A (YAMANOUCHI PHARMA CO. LTD) 5 July 1995	ACEUTICAL	1,3-17, 19-28, 30-38	
	see claims 1,5,6 see page 3, line 1 - line 29 see page 3, line 49 - page 5, line see page 8; table 3 see page 25; examples 12-14	ne 2 -/		
X Furt	Iner documents are listed in the continuation of box C.	X Patent family members are listed	I in annex.	
"A" docume consider filing of the control of the co	ent defining the general state of the art which is not dered to be of particular relevance document but published on or after the international date ent which may throw doubts on pnority claim(s) or is cited to establish the publication date of another in or other special reason (as specified) sent referring to an oral disclosure, use, exhibition or means ent published prior to the international filling date but han the pnority date claimed	"T" later document published after the int or priority date and not in conflict will cited to understand the principle or t invention "X" document of particular relevance; the cannot be considered novel or cannot novel or inventive step when the deciment of particular relevance; the cannot be considered to involve an adocument is combined with one or menta, such combination being obvious the art. "&" document member of the same pater	In the application but heary underlying the claimed invention of the considered to locument is taken alone claimed invention inventive step when the hore other such docu-	
Date of the	actual completion of theinternational search	Date of mailing of the international se	earch report	
8	B December 1997	05/01/1998		

European Patent Office, P.S. 5818 Patentiaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016

Name and mailing address of the ISA

Form PCT/ISA/210 (second sheet) (July 1992)

Authorized officer

Ventura Amat, A

2

INTERNATIONAL SEARCH REPORT

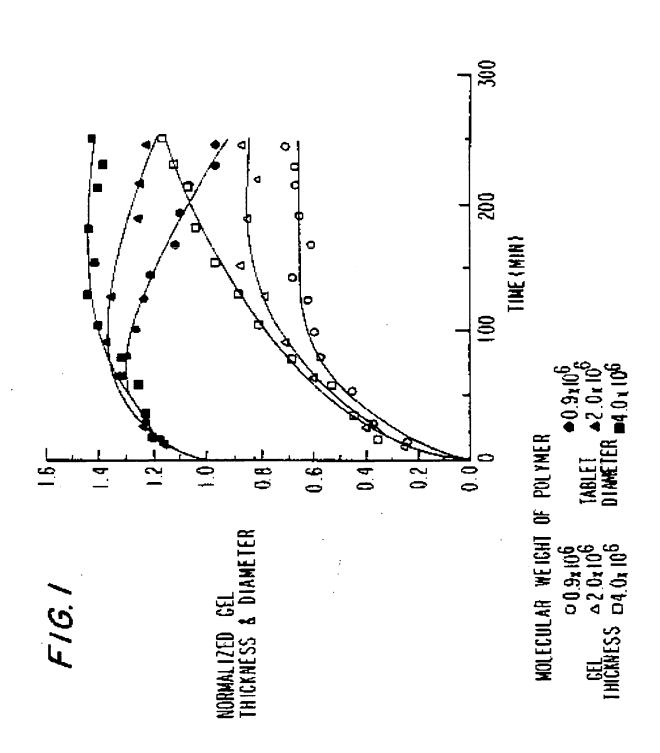
Intern. Ial Application No PCT/US 97/10737

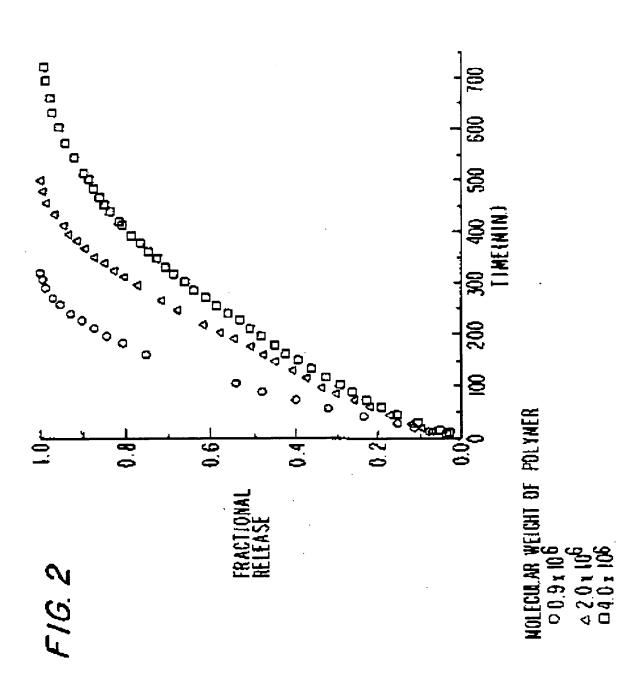
		PC1/US 9//10/3/			
C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT					
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.			
A	EP 0 231 826 A (FARMA S.A.) 12 August 1987 see the whole document	1-39			
P , X	WO 96 26718 A (TEMPLE UNIVERSITY OF THE COMMONWEALTH SYSTEM OF HIGHER EDUCATION) 6 September 1996 see the whole document	1-39			
ļ					
	·				

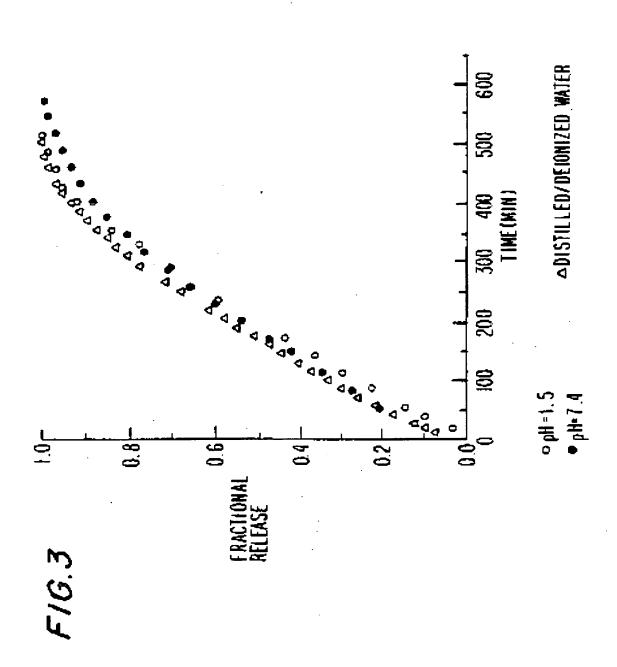
Information on patent family members

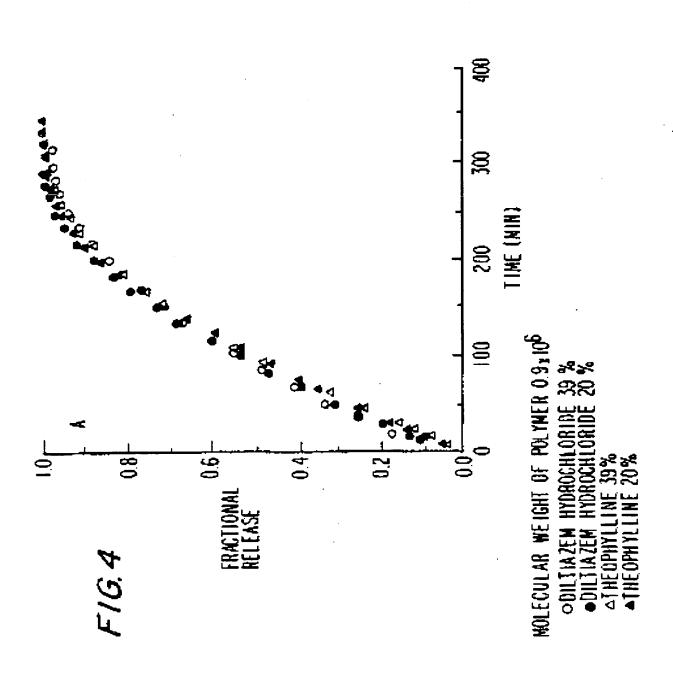
PCT/US 97/10737

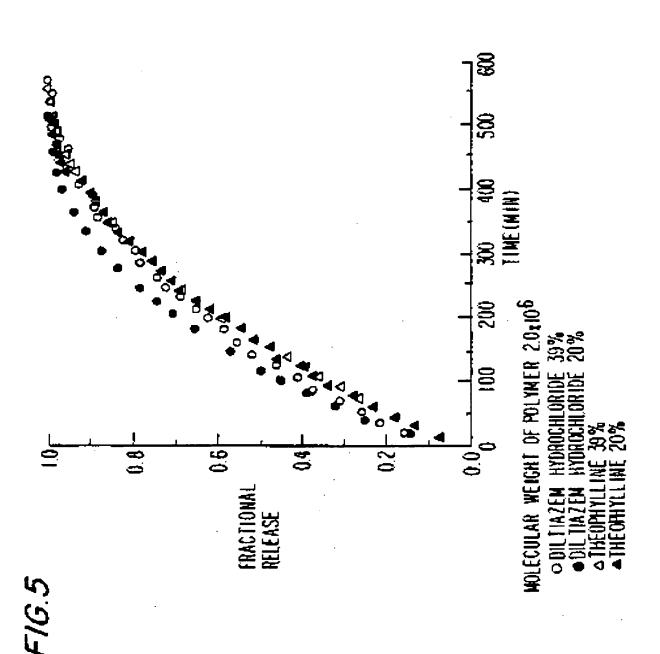
Patent document cited in search report		Publication date		Patent family member(s)	Publication date
EP 661045	A	05-07-95	AU	682827 B	23-10-97
			AU	4983893 A	12-04-94
			BG	99503 A	31-01-96
			FI	951226 A	16-03-95
			NO	951036 A	17-03-95
			SK	33895 A	08-11-95
			CA	2144077 A	31-03-94
			CN	1091004 A	24-08-94
			CZ	9500679 A	13-09-95
		•	HU	72324 A	29-04-96
			WO	9406414 A	31-03-94
			NZ	255579 A	26-03-96
			PL	308137 A	24-07-95
			ZA	9306798 A	14-04-94
EP 231826	Α	12-08-87	US	4837032 A	06-06-89
			CA	1273876 A	11-09-90
			DE	3774889 A	16-01-92
			ES	2055689 T	01-09-94
			JP (53057523 A	12-03-88
NO 9626718	3 A	06-09-96	AU	5171196 A	18-09-96

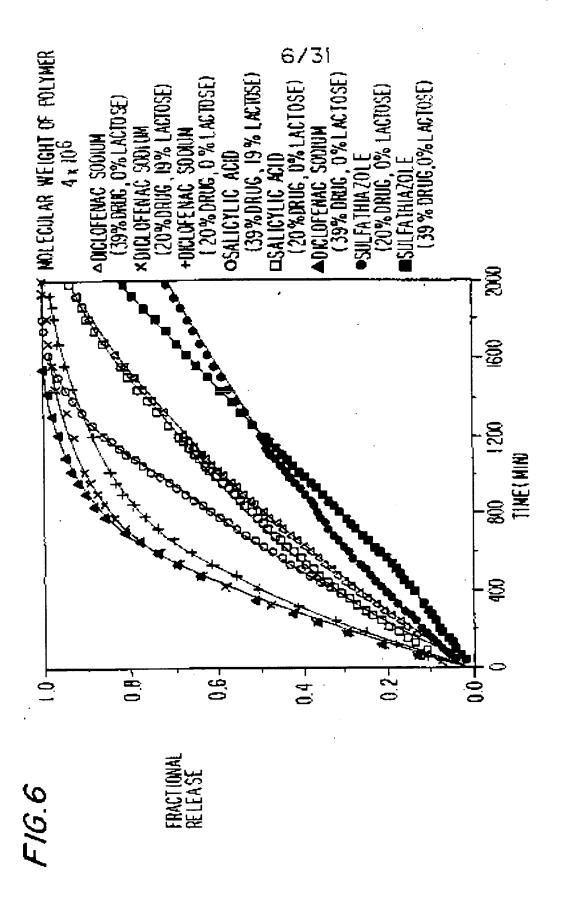


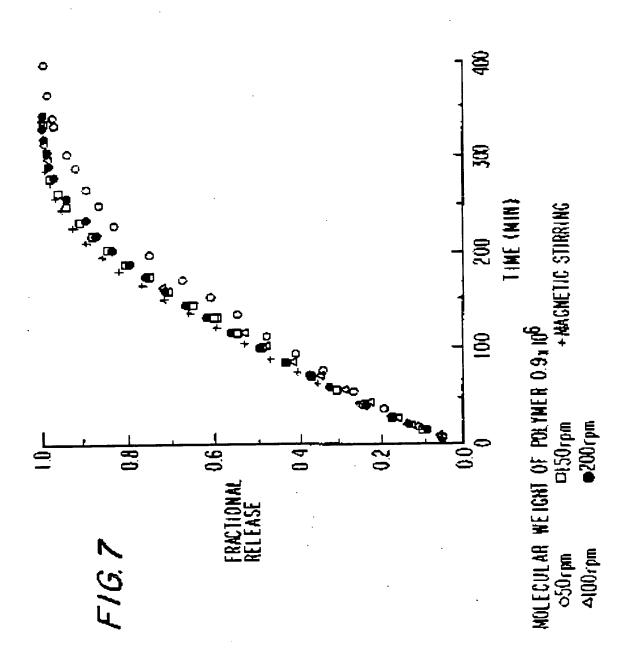


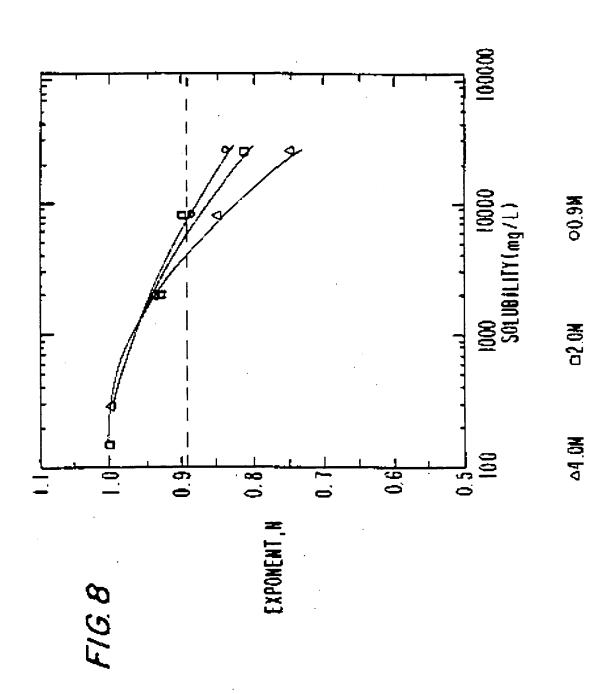


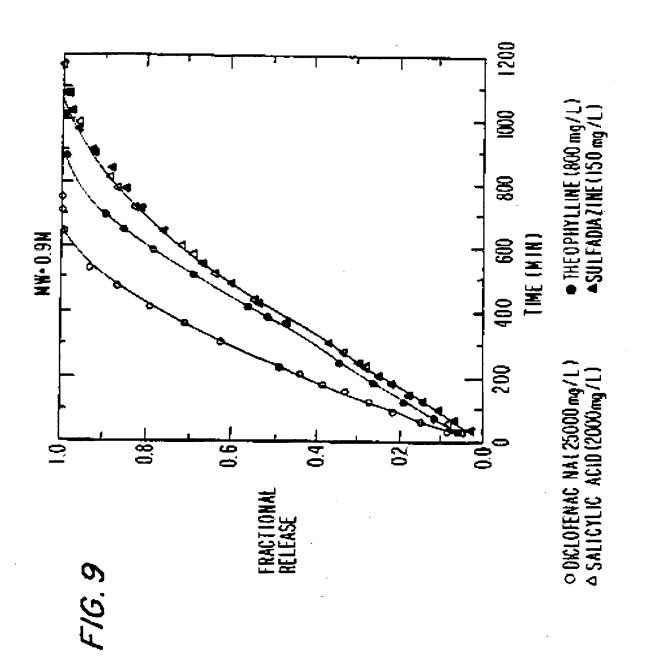




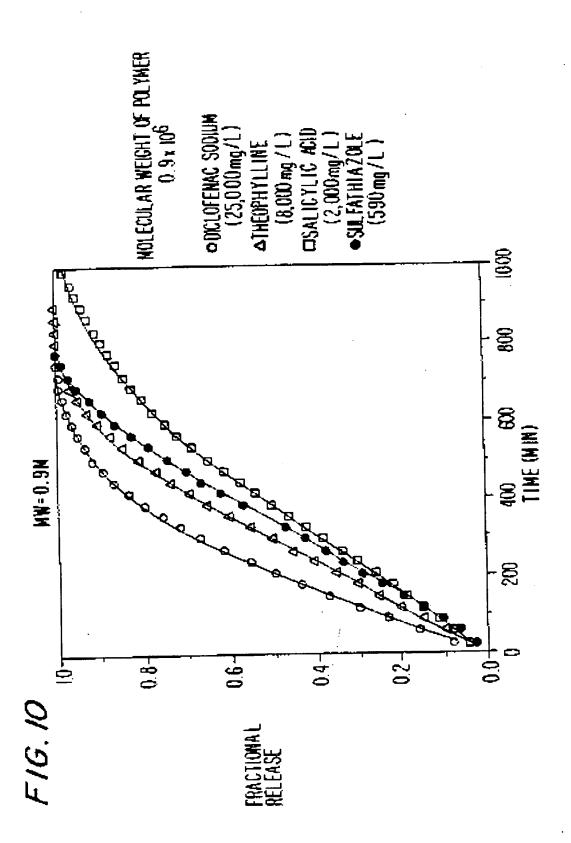


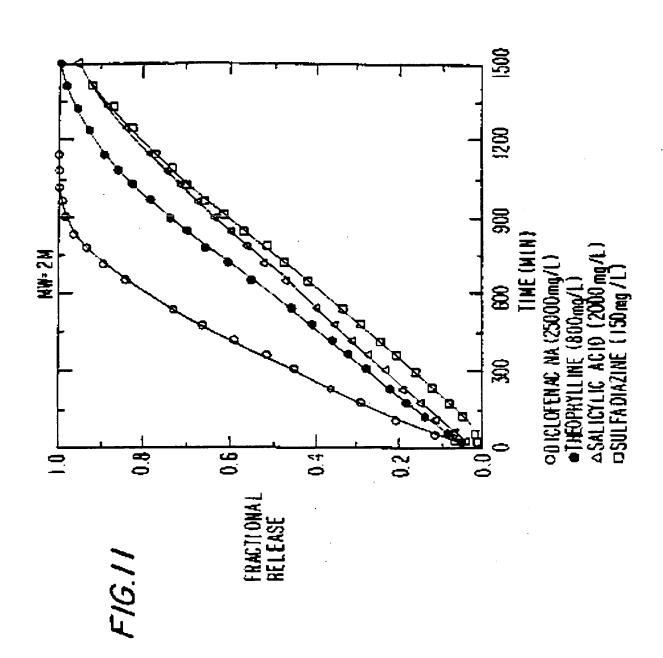


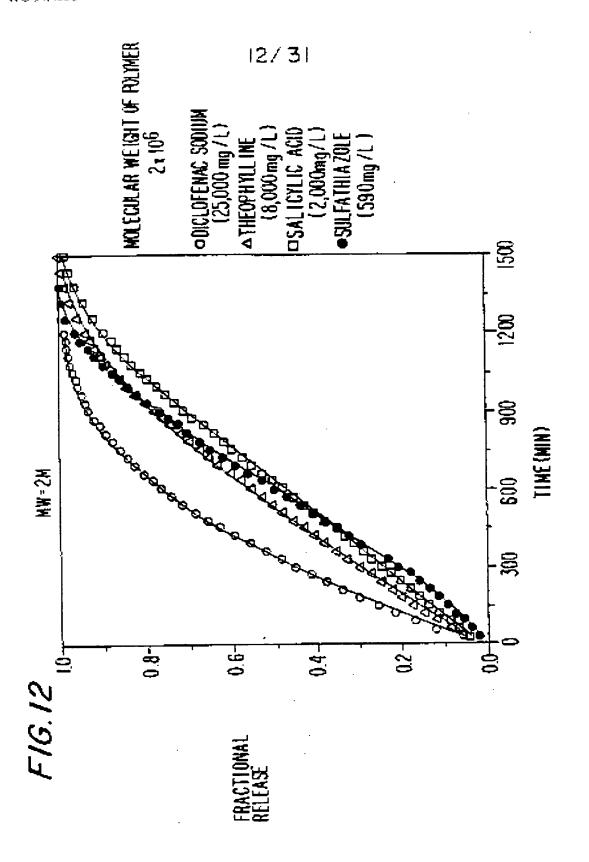


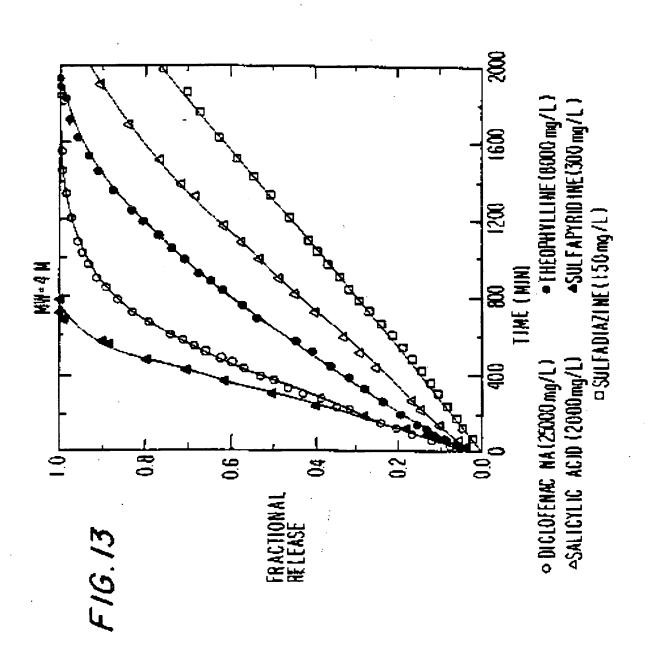


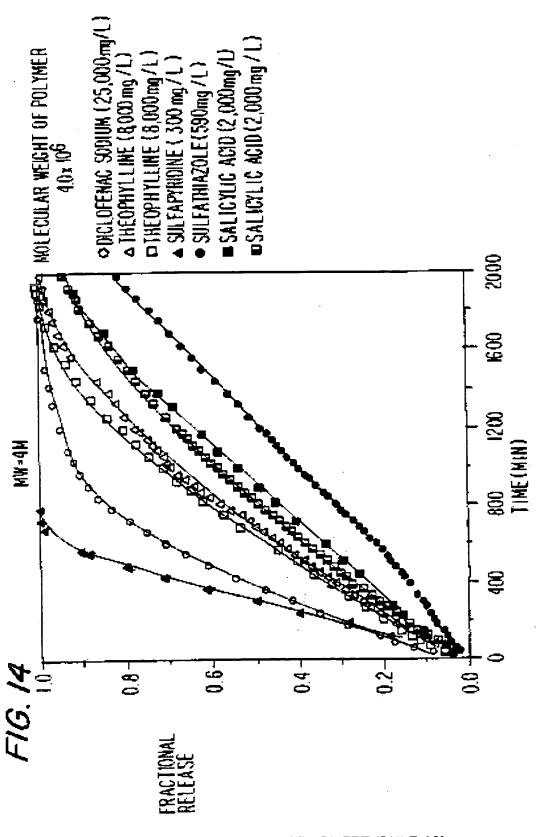
10/31



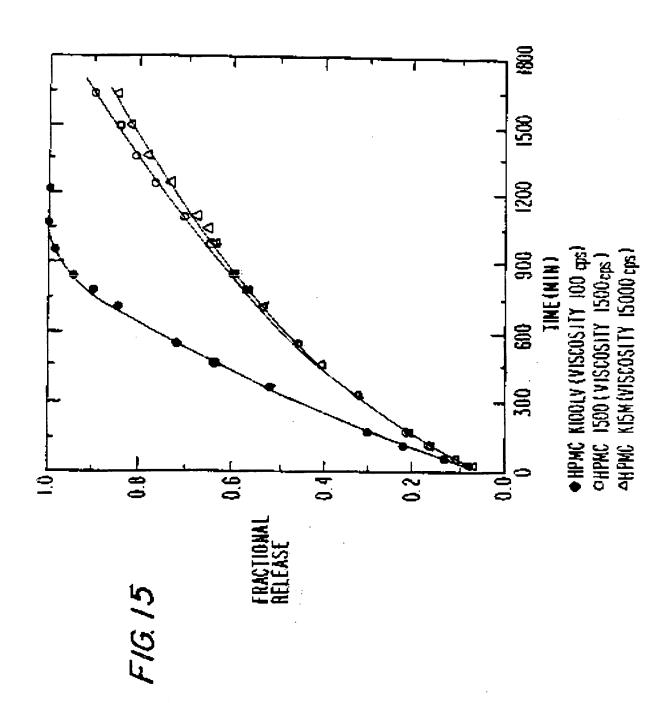


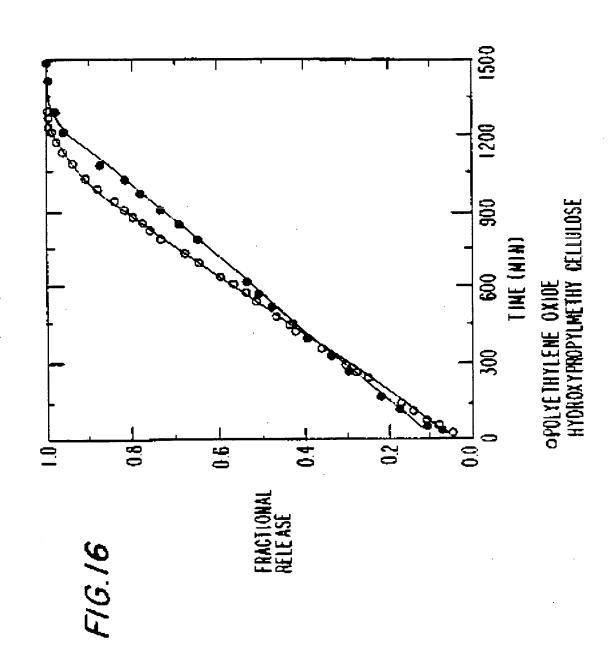


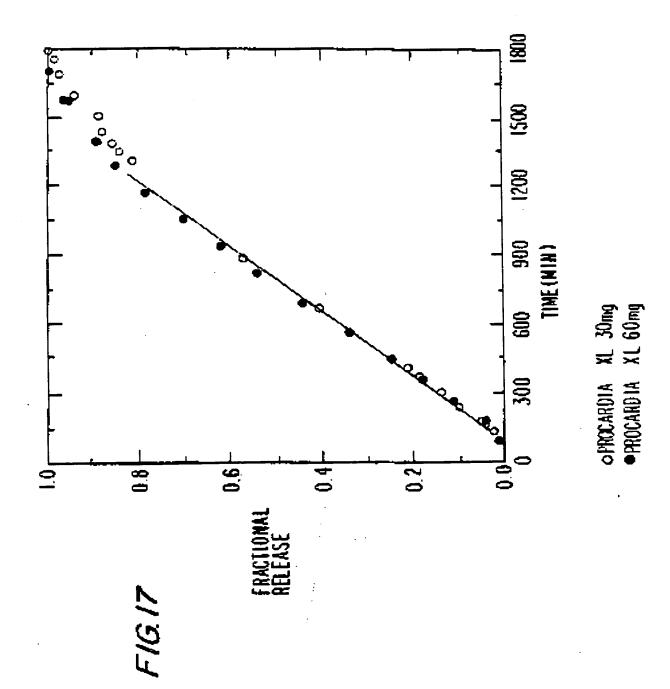


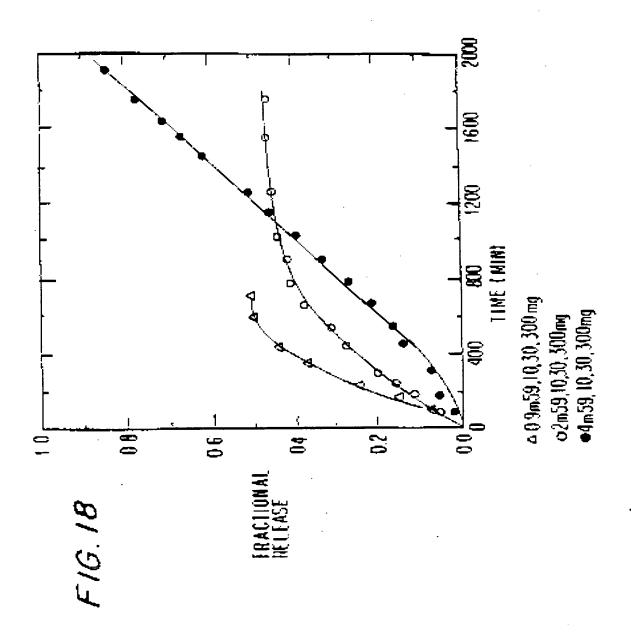


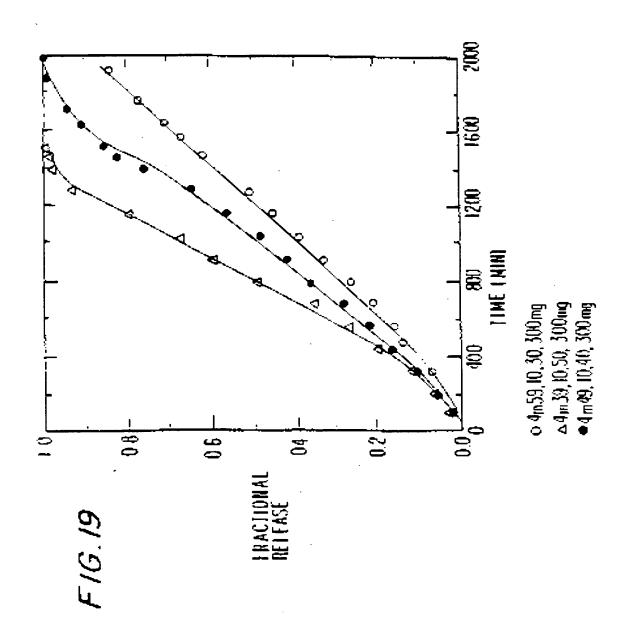
SUBSTITUTE SHEET (RULE 26)





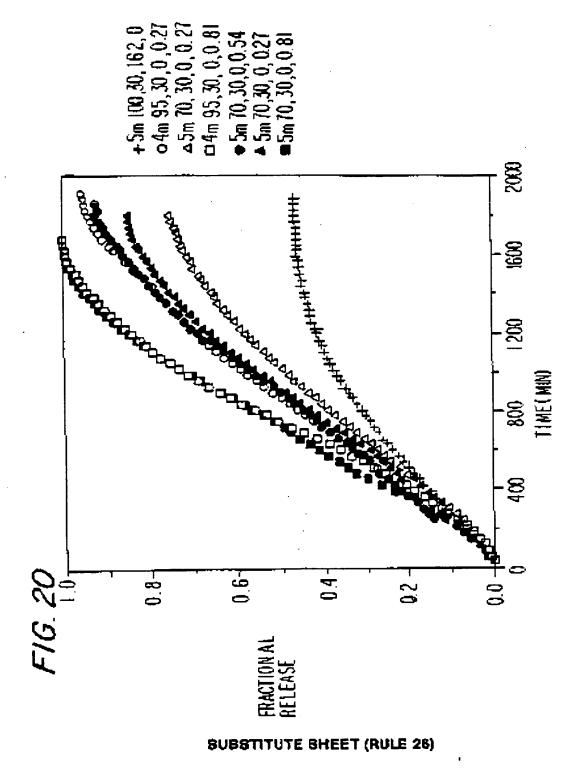


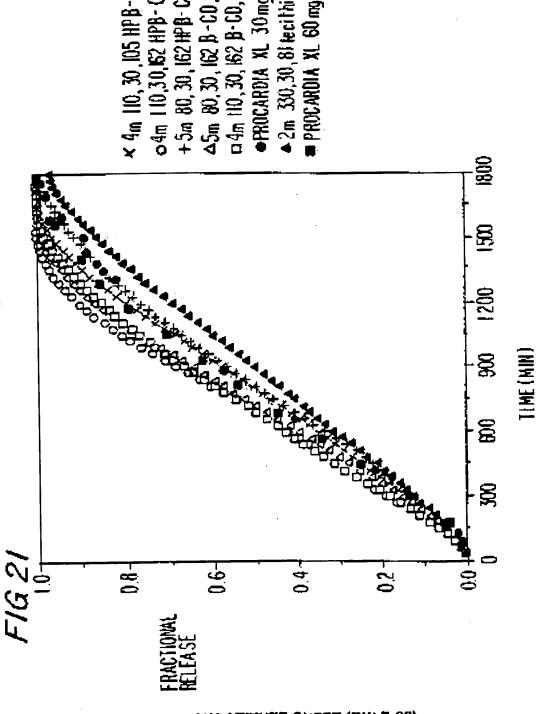




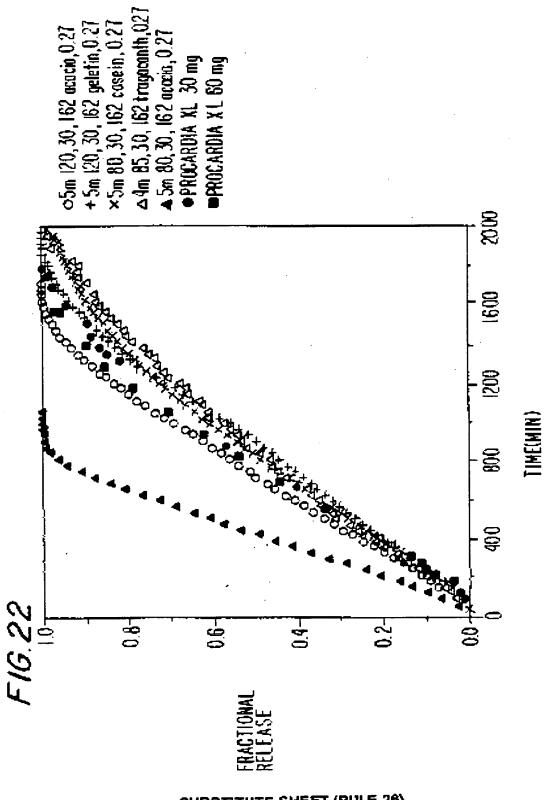
SUBSTITUTE SHEET (RULE 28)

20/31

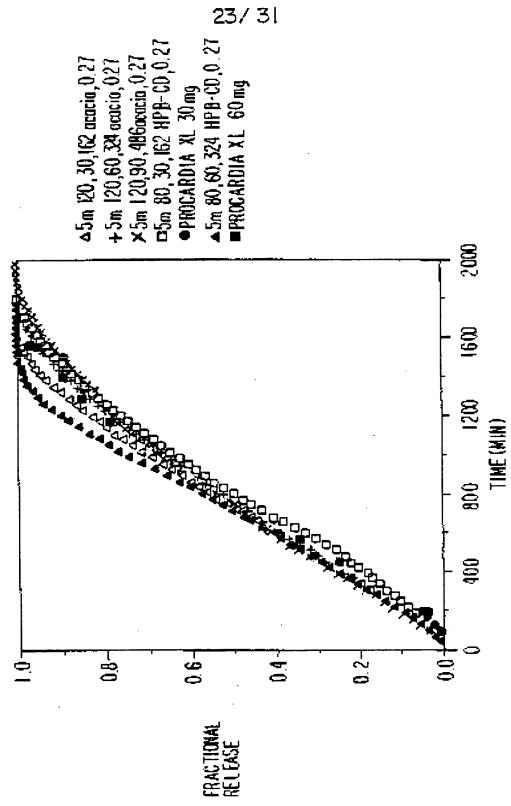




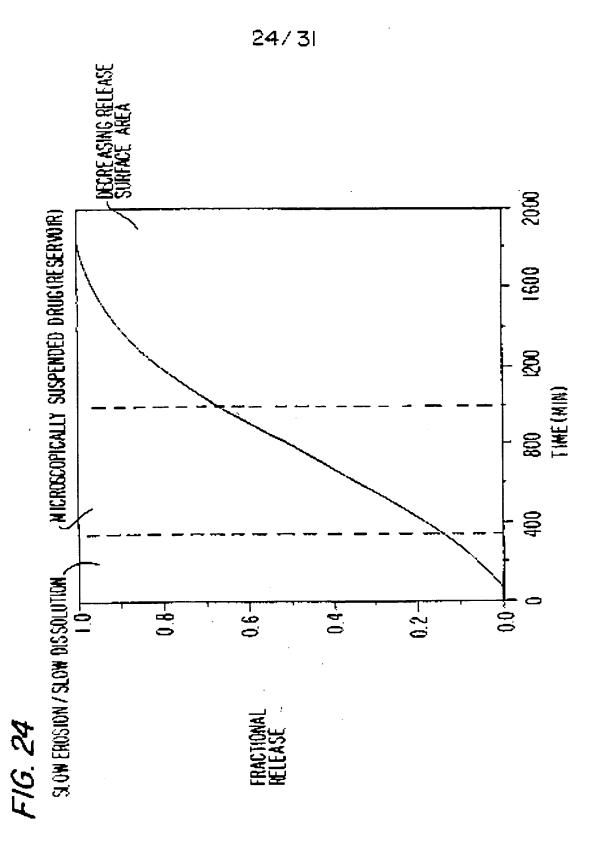
SUBSTITUTE SHEET (RULE 25)

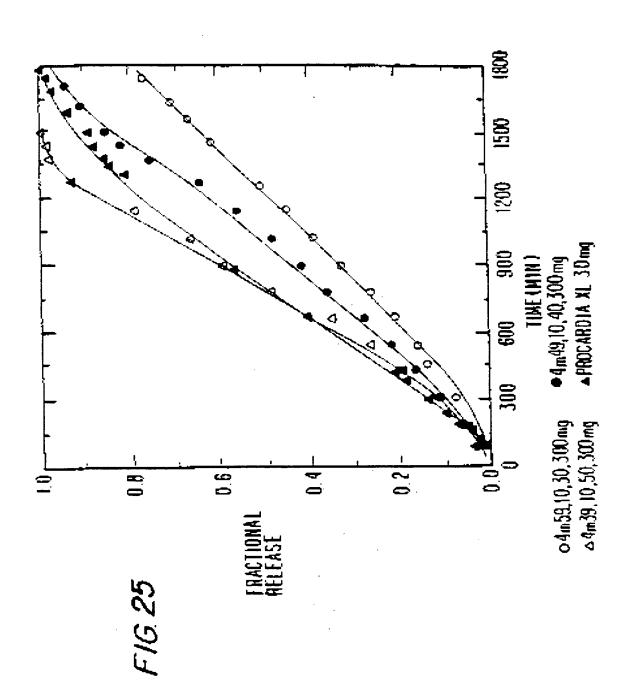


SUBSTITUTE SHEET (RULE 26)

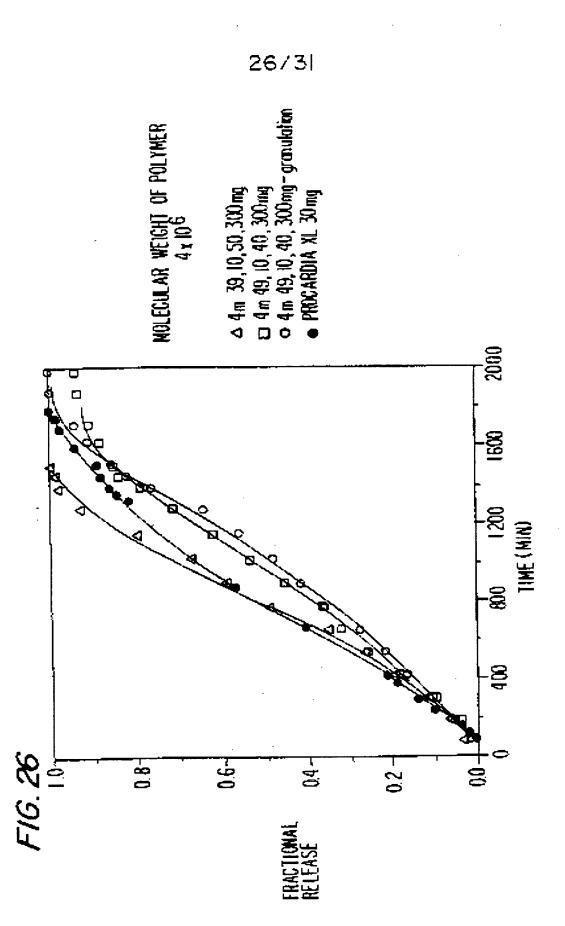


FK

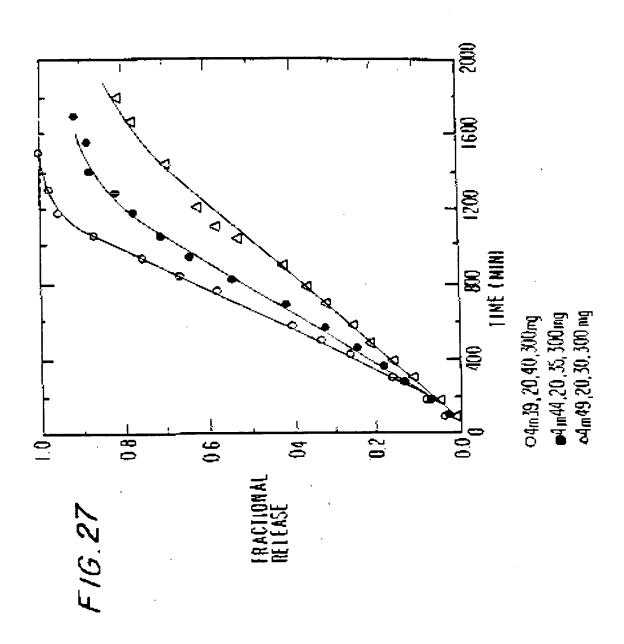




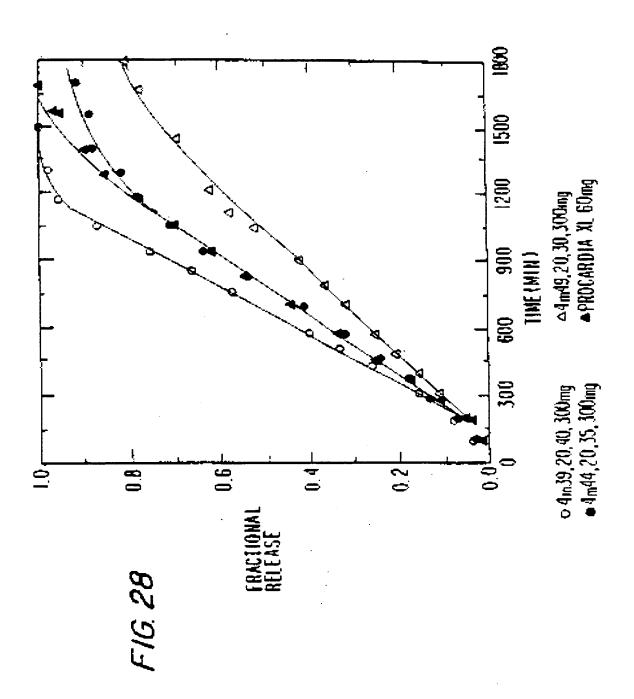
SUBSTITUTE SHEET (RULE 26)

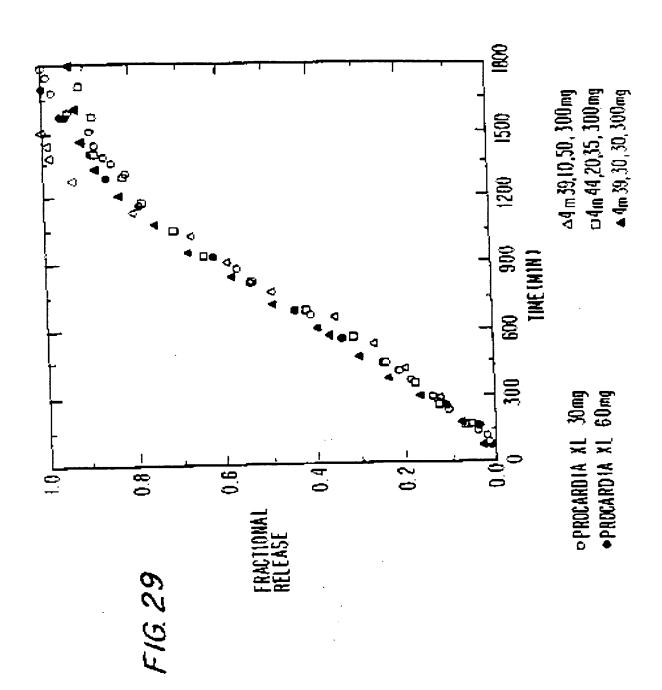


SUBSTITUTE SHEET (RULE 26)

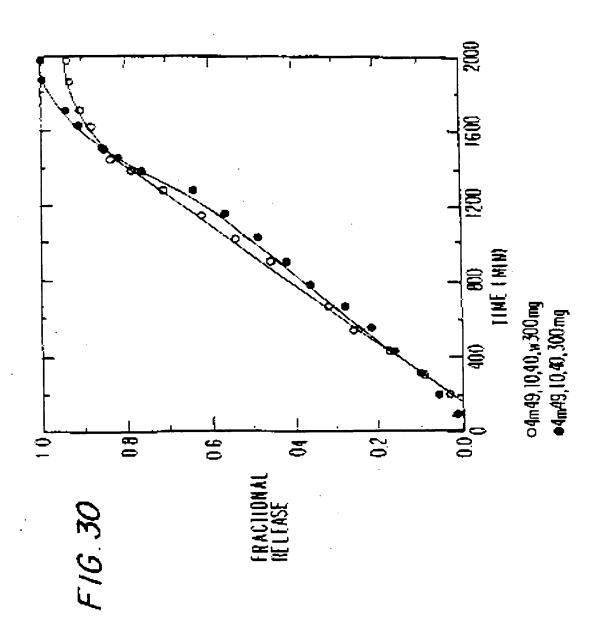


SUBSTITUTE SHEET (RULE 26)





SUBSTITUTE SHEET (RULE 26)



SUBSTITUTE SHEET (RULE 26)

